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Certified by



Jon W Dudas

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

Express Mail Label No. ET866264285US

INVENTOR(S)					
Given Name (first and middle (if any))		Family Name or Surname		Residence (City and either State or Foreign Country)	
John A.		Gelardi		Kennebunkport, ME	
Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
Child-Resistant Pill Packaging System and Method for Making Same					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
<input checked="" type="checkbox"/> Customer Number:		27997			
OR					
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages 15		<input type="checkbox"/> CD(s), Number _____			
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets 10		<input checked="" type="checkbox"/> Other (specify) return-receipt postcard			
<input checked="" type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT					
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.				FILING FEE Amount (\$)	
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the filing fees.				160.00	
<input checked="" type="checkbox"/> The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 50-1058					
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government					
<input checked="" type="checkbox"/> No.					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____					

Respectfully submitted,

SIGNATURE

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[Page 1 of 1]

Date November 13, 2003

REGISTRATION NO. 30,210

(if appropriate)

Docket Number: 103.0033.PROV

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the PTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**CHILD-RESISTANT SYSTEM FOR PACKAGING
MEDICATION DOSAGE UNITS AND METHODS FOR MAKING SAME**

BACKGROUND OF THE INVENTION

5 Field of the Invention

The present invention relates generally to improvements in the field of packaging, and more particularly to advantageous aspects of a child-resistant system for packaging medication dosage units and methods for making same.

10 Description of Prior Art

In the pharmaceutical industry, many types of packaging have been developed for pills, capsules, and the like. One type of packaging is the blister package, also referred to in the industry simply as a "blister." In a typical blister, a thermoforming technique is used to fabricate a plastic shell containing individual chambers for holding pills. A backing is then affixed to the back of the shell, thereby enclosing each pill in its own chamber. Individual pills are released from the blister by applying pressure to the pill through the plastic shell. The pill chamber collapses as the pill is driven through the backing at the base of the pill compartment. That portion of the backing ruptures, and the pill is released from the blister through the resulting opening.

20 For its combination drug therapy products, a pharmaceutical company may wish to place more than one medication in a single package. In certain situations, it may be desirable to package together, in a single unit, a first medication requiring a child-resistant container and a second medication not requiring a child-resistant container.

SUMMARY OF THE INVENTION

These and other issues are addressed by the present invention, aspects of which provide a medication dosage unit packaging system that includes a tray for holding a blister containing a plurality of unit chambers. The blister is divided into a general access zone containing at least one general access unit chamber and a restricted access zone containing at least one restricted access unit chamber. The general access zone and the restricted access zone are separated by a chamber-free zone. A retaining cap holds the blister package in the tray. The retaining cap and the tray have therebetween a guide post fitting into a guide slot in the chamber-free zone in the blister. The guide post and the guide slot are positioned in the tray such that when a blister package is held in the tray by the retaining cap, the blister is slidable between a first position in which only the general access zone of the blister is accessible, and a second position in which both the general access zone and the limited access zone of the blister are accessible. A child-resistant hinging cap is hingeably mounted into the tray, such that when the hinging cap is in a closed position, it locks the blister package in its first position, and when the hinging cap is in an opened position, it allows the blister package to be slid into its second position.

Additional features and advantages of the present invention will become apparent by reference to the following detailed description and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figs. 1 and 2 show exploded perspective views, from above and below, of a packaging system according to a first aspect of the invention.

Figs. 3-6 show a series of perspective views illustrating the operation of the hinging cap in the packaging system shown in Figs. 1 and 2.

Figs. 7-9 show a series of perspective views illustrating a further aspect of the invention in which an outer sleeve is provided for the packaging system shown in Figs. 1 and 2.

Fig. 10 shows a flowchart of a method for packaging units according to a further aspect of the invention.

5

DETAILED DESCRIPTION

As used herein, the term "unit" refers generally to pills, capsules, caplets, and other medications, or the like, which may suitably be packaged in a blister. The term "restricted access" refers to units to be stored in a child-resistant manner, and the term "general access" refers to units that need not be stored in a child-resistant manner.

10 An aspect of the invention provides a system for packaging restricted access and general access units together in a single package. As described in greater detail below, the restricted access and general access units are packaged together in a specially designed blister. The blister is slidably mounted into a tray, such that the blister is slidable between a first position, in which
15 only the general access units are accessible, and a second position, in which both the general access units and restricted access units are accessible. As described below, the packaging system includes a child-resistant hinging cap for locking the blister in its first position. When the child-resistant hinging cap is opened, the blister is unlocked and may be slid into its second position to gain access to the restricted access units. After one or more of the restricted units has
20 been removed from the blister, the user of the package may relock the package by sliding the blister back from its second position to its original first position, and reclosing the hinging cap.

Thus, a package according to the present invention provides easy access to the general access units, while providing a child-resistant system to limit access to restricted access units.

The easy access to the general access units is desirable for elders, or for other people with impaired dexterity. In addition, the package frame provides leverage that may be useful in popping both the restricted access and general access units out of the blister.

Figs. 1 and 2 show exploded perspective views, from above and below, of a packaging system 10 according to a first aspect of the invention. The packaging system 10 includes three components: a blister 100, a tray 200 into which the blister is slidably mounted, and a blister retaining cap 300 that is used to mount the blister 100 into the tray 200. In the present embodiment of the invention, the blister 100 is fabricated using a thermoforming technique, and the tray 200 and blister retaining cap 300 are fabricated using an injection molding technique.

Other fabrication techniques may be used without departing from the spirit of the invention.

According to an aspect of the invention, the mounting of the blister 100 into the tray 200 is performed by a manufacturer or distributor prior to sale to a customer. Thus, a customer is provided with an assembled package, in which the blister 100 has been permanently mounted into the tray 200. It is contemplated that this assembled package will be disposable. However, it would be possible to modify the packaging system 10 so that the tray 200 and blister retaining cap 300 are reusable by replacing a used blister 100 with a fresh one.

The blister 100 includes a plurality of unit chambers 102 and 104, and a backing 106. A unit contained in a chamber 102 and 104 is released from the chamber by applying downward pressure onto the chamber to cause the chamber to collapse and to cause the unit contained therein to be driven against the portion of the backing 106 at the base of the chamber. That portion of the backing 106 ruptures, releasing the unit through the resulting opening.

According to an aspect of the invention, the blister chambers are divided into two groups. A first group of chambers 102 contains general access units. A second group of chambers 104

contains restricted access units. The present embodiment of the invention includes a 6 x 2 matrix of general access chambers 102, and a 1 x 2 matrix of restricted access chambers 104. However, it will be appreciated in light of the present discussion that the dimensions of these matrices may be freely modified without departing from the spirit of the present invention. The region of the blister 100 containing the general access chambers 102 is referred to herein as the "general access zone." The region of the blister 100 containing the restricted access chambers 104 is referred to herein as the "restricted access zone."

As further shown in Figs. 1 and 2, the blister 100 further includes a region 108 between the general access zone and the restricted access zone in which there are no unit chambers. This region 108 is referred to herein as a "chamber-free zone." The chamber-free zone 108 includes a slot 110 extending axially down its length. As explained below, this slot 110 is used to define a path having a predetermined length for sliding the blister 100 between its first and second positions.

It should be noted that it would be possible to use the blister 100 to package units without the tray 200 and blister retaining cap 300. The blister 100 would be used in this way when the child-resistant feature of the packaging system 10 is not required. Thus, a pharmaceutical company would have the option of providing the medication in both child-resistant and non-child-resistant versions.

The tray 200 includes a frame 202 with end walls 204 and 206 and side walls 208 and 210. The tray 200 includes a pair of general access windows 212 and 214 corresponding in position to the general access chambers 102 in the blister 100 in the assembled package. The tray 200 further includes a pair of restricted access windows 216 and 218. As described below, when the blister 100 is slid into its second position, the restricted access chambers 104 on the

blister 100 are aligned with the restricted access windows 216 and 218. As shown in Figs. 1 and 2, the blister 100 is oriented in the tray 200 so that the blister backing 106 is positioned between the unit chambers 102 and 104 and the access windows 212, 214, 216 and 218. A unit is released from a chamber by exerting pressure on the chamber in the direction of the windows
5 corresponding to that chamber, which causes the unit to be driven through the backing and window to release the unit. It will be seen from Fig. 2 that the tray frame 202 provides structural support that facilitates the driving of units through the backing. This aspect of the invention may be helpful for patients with impaired dexterity. As discussed below, the restricted access chambers 104 are aligned with the restricted access windows 216 and 218 only when the blister
10 blister 100 is slid into its second position.

The blister 100 is held in the tray 200 by the blister retaining cap 300. As shown in Figs. 1 and 2, the blister retaining cap 300 includes a base 302 and three walls 304, 306, and 308 that together form a hood. This hood forms part of a compartment that houses the restricted access chambers 104 when the blister 100 is in its first position. The blister retaining cap 300 further
15 includes a central guide post 310. In the present embodiment of the invention, this guide post is hollow and fits over a corresponding mounting post 220 on the tray 200. The guide post 310 may be attached to the mounting post 220 using an adhesive or other suitable technique. If desired, the guide post 310 may be releasably mounted to the mounting post 220. This arrangement would allow the tray 200 and blister retaining cap 300 to be reused with a fresh
20 blister 100.

The guide post 310 of the blister retaining cap 300 is mounted to the tray mounting post 220 with the guide post 310 extending through the blister guide slot 110. When mounted

together, the upper edges of the blister retaining cap walls 304, 306, and 308 hold the chamber-free portion 108 of the blister 100 against the inner surface of the tray 200.

After it is mounted into the tray 200, the blister 100 is slidable in an axial direction. The axial movement of the blister 100 within the tray 200 is limited by the guide post 310 and guide slot 110. In the blister's first position, the guide post 310 butts up against a first end of the guide slot 110. In the blister's second position, the guide post 310 butts up against a second end of the guide slot 110. The lateral movement of the blister 100 within the tray 200 is limited by the side walls 208 and 210 of the tray 200.

Figs. 3-6 are a series of perspective views of the packaging system 10, illustrating the structure and operation of a hinging cap 250. In the present embodiment of the invention, the hinging cap 250 is formed as part of the tray 200 in an injection molding process. The hinging cap 250 is formed in an open configuration, and is closed when the package is assembled. However, it would also be possible to form the hinging cap 250 as a separate unit that is then hingeably mounted to the tray 200.

Fig. 3 shows the hinging cap 250 in its closed position, and Fig. 4 shows the hinging cap 250 in an open position, with the blister 100 in its first position. Fig. 5 shows the hinging cap 250 in an open position, with the blister 100 slid into its second position. Fig. 6 shows a perspective view from below of the packaging system 10 with the hinging cap 250 in an open position.

As shown in Figs. 3 and 4, the hinging cap includes a flap 252 that is attached to an end wall 204 of the tray 200 by a hinge 254. When the hinging flap 252 is closed, it forms a flat surface that is substantially continuous with the base 302 of the blister retaining cap 300.

As further shown in Fig. 4, the hinging cap 250 includes a pair of ribs 256 and 258 protruding from the interior surface of the flap 252. The ribs 256 and 258 are shaped such that they butt up against the blister's restricted access chambers 104 when the hinging cap 250 is in its closed position. The ribs 256 and 258 serve to lock the blister 100 into its first position when the hinging cap 250 is closed. When the hinging cap 250 is opened, the ribs 256 and 258 are clear of the restricted access chambers 104, allowing the blister 100 to be slid into its second position.

As further shown in Figs. 4 and 6, the hinging cap 250 includes a pair of buttons 260 and 262 that protrude outwardly from a pair of resiliently deformable struts 264 and 266. The buttons 260 and 262 are dimensioned and positioned to fit closely within a pair of stirrups 268 and 270 formed in the side walls of the tray 200. When the hinging cap 250 is in its closed position, the buttons 260 and 262 protrude outwardly through the stirrups 268 and 270, engaging the edges thereof, locking the hinging cap 250 in its closed position. As shown in Fig. 4, the hinging cap 250 is opened by pressing the buttons 260 and 262 inward in the direction of arrows 272 and 274 so that they are sufficiently clear of the stirrups 268 and 270 to allow the hinging cap 250 to be swung open in the direction of arrow 276.

It is contemplated that a user of the package will use a thumb and finger of a first hand to press the two buttons 260 and 262 inward, and use the second hand to swing the hinging cap 250 open. In order to facilitate the gripping of the hinging cap 250 by the second hand, a semicircular well 312 is provided in the base 302 of the blister retaining cap 300. The hinging cap 250 includes an ear 278 corresponding in position to the well. The hinging cap 250 may be reclosed by swinging it downward so that the buttons 260 and 262 once again engage the stirrups 268 and 270. The buttons 260 and 262 have a rounded surface to allow the buttons to be slid

into position without having to use a thumb and finger to inwardly deflect the buttons 260 and 262.

As illustrated in Fig. 5, the blister 100 is slid along the direction of arrow 280 into its second position. In this second position, the restricted access chambers 104 have been slid out from under the blister retaining cap 300 and are now visible. Further, in the second position, the restricted access chambers 104 are aligned, as shown in Fig. 6, with restricted access windows 216 and 218. The units in the restricted access chambers 104 may now be released from the blister 100 by applying pressure to the restricted access chambers 104 in the direction of arrow 282. As discussed above, applying pressure in this manner causes the restricted access chambers 104 to collapse, driving the units contained therein through the backing 106 and windows 216 and 218.

It will be appreciated that the hinging cap 250 is child resistant, because it requires the use of both hands and a certain amount of hand-eye coordination to open the hinging cap 250. In addition, even if a child manages to open the hinging cap 250, the child may find it difficult to slide the blister 100 into its second position to align the restricted access chambers with windows 216 and 218.

Figs. 7-9 show a series of diagrams illustrating a further aspect of the invention in which the packaging system 10 is encased in an outer sleeve 400. As shown in Fig. 7, the sleeve includes first and second open ends 402 and 404 and is shaped to fit closely around the entire packaging system 10. The packaging system 10 may be slid out of either end of the outer sleeve 400.

As shown in Fig. 7, when the packaging system 10 is slid out of the first end 402 of the outer sleeve 400, the hinging cap 250 is exposed without having to completely remove the

packaging system 10 from the outer sleeve 400. As shown in Fig. 8, the hinging cap 250 may be opened to provide access to the restricted access chamber 104 of the blister 100. As shown in Fig. 9, when the packaging system 10 is slid out of the second end 404 of the outer sleeve 400, the general access chambers 102 of the blister are accessible, again without have to completely
5 remove the packaging system 10 from the outer sleeve 400.

Fig. 10 shows a flowchart of a method 500 for packaging units according to a further aspect of the invention. In step 502, units are packaged into a blister, which includes a general access zone containing at least one general access unit chamber and a restricted access zone containing at least one restricted access unit chamber, the general access zone and the restricted
10 access zone being separated by a chamber-free zone. In step 504, the blister is loaded into a receiving tray. In step 506, a retaining cap is used to hold the blister package in the tray, the retaining cap and the tray including therebetween a guide post fitting into a guide slot in the chamber-free zone in the blister, the guide post and guide slot being positioned in the tray such that when a blister package is held in the tray by the retaining cap, the blister is slidable between
15 a first position in which only the general access zone of the blister is accessible, and a second position which both the general access zone and the limited access zone of the blister are accessible, the blister being held in the first position by a child-resistant hinging cap that is hingeably mounted into the tray, such that when the hinging cap is in a closed position, it locks the blister package in its first position, and when the hinging cap is in an opened position, it
20 allows the blister package to be slid into its second position.

It should be noted that the above-described packaging system and method may also be used in conjunction with items other than medication dosage units. It will be appreciated that the described system and method may also be used to package any other types of items that can

suitably be packaged in a blister. In addition, it would also be possible to use the present invention to package together medication dosage units with other types of items.

While the foregoing description includes details which will enable those skilled in the art to practice the invention, it should be recognized that the description is illustrative in nature and
5 that many modifications and variations thereof will be apparent to those skilled in the art having the benefit of these teachings. It is accordingly intended that the invention herein be defined solely by the claims appended hereto and that the claims be interpreted as broadly as permitted by the prior art.

I claim:

1. A packaging system, comprising:

a tray for holding a blister containing a plurality of unit chambers, the blister being divided into a general access zone containing at least one general access unit chamber and a
5 restricted access zone containing at least one restricted access unit chamber, the general access zone and the restricted access zone being separated by a chamber-free zone,

a retaining cap for holding the blister package in the tray, the retaining cap and the tray having therebetween a guide post fitting into a guide slot in the chamber-free zone in the blister, the guide post and guide slot being positioned in the tray such that when a blister package is held
10 in the tray by the retaining cap, the blister is slidable between a first position in which only the general access zone of the blister is accessible, and a second position in which both the general access zone and the limited access zone of the blister are accessible,

a child-resistant hinging cap that is hingeably mounted into the tray, such that when the hinging cap is in a closed position, it locks the blister package in its first position, and when the
15 hinging cap is in an opened position, it allows the blister package to be slid into its second position.

2. The packaging system of claim 1, wherein the tray includes at least one general access window for providing access to the general access zone when the blister is in its first and second positions and at least one restricted access window for providing access to the restricted
20 access zone when the blister is in its second position.

3. The packaging system of claim 1, wherein the retaining cap includes a hood that covers the restricted access zone of the blister when the blister is in its first position.

4. The packaging system of claim 1, wherein the hinging cap includes a pair of buttons protruding from a corresponding pair of resiliently deflectable struts, the buttons engaging respective stirrups formed in the tray when the hinging cap is closed, the hinging cap being openable by inwardly deflecting both buttons such that they clear the stirrups.
- 5 5. The packaging system of claim 1, further including a sleeve into which the assembled tray, blister package and retaining cap are slid.
6. The packaging system of claim 5, wherein the sleeve is open at first and second ends, such that when the assembled tray, blister package and retaining cap are slid out of the first end of the sleeve, the general access zone of the blister is accessible, and when the assembled
- 10 tray, blister package and retaining cap are slid out of the second end of the sleeve, the hinging cap is accessible.
7. A method for packaging units, comprising:
- (a) packaging units into a blister, the blister including a general access zone containing at least one general access unit chamber and a restricted access zone containing at
- 15 least one restricted access unit chamber, the general access zone and the restricted access zone being separated by a chamber-free zone;
- (b) loading the blister into a receiving tray;
- (c) using a retaining cap to hold the blister package in the tray, the retaining cap and the tray including therebetween a guide post fitting into a guide slot in the chamber-free zone in
- 20 the blister, the guide post and guide slot being positioned in the tray such that when a blister package is held in the tray by the retaining cap, the blister is slidable between a first position in which only the general access zone of the blister is accessible, and a second position which both the general access zone and the limited access zone of the blister are accessible, the blister being

held in the first position by a child-resistant hinging cap that is hingeably mounted into the tray, such that when the hinging cap is in a closed position, it locks the blister package in its first position, and when the hinging cap is in an opened position, it allows the blister package to be slid into its second position.

- 5 8. The method of claim 7, further including:
- (d) loading the assembled tray, blister, and blister retaining cap into a sleeve.

ABSTRACT

A medication dosage unit packaging system includes a tray for holding a blister containing a plurality of unit chambers. The blister is divided into a general access zone containing at least one general access unit chamber and a restricted access zone containing at least one restricted access unit chamber. The general access zone and the restricted access zone are separated by a chamber-free zone. A retaining cap holds the blister package in the tray. The retaining cap and the tray have therebetween a guide post fitting into a guide slot in the chamber-free zone in the blister. The guide post and the guide slot are positioned in the tray such that when a blister package is held in the tray by the retaining cap, the blister is slidable between a first position in which only the general access zone of the blister is accessible, and a second position which both the general access zone and the limited access zone of the blister are accessible. A child-resistant hinging cap is hingeably mounted into the tray, such that when the hinging cap is in a closed position, it locks the blister package in its first position, and when the hinging cap is in an opened position, it allows the blister package to be slid into its second position.

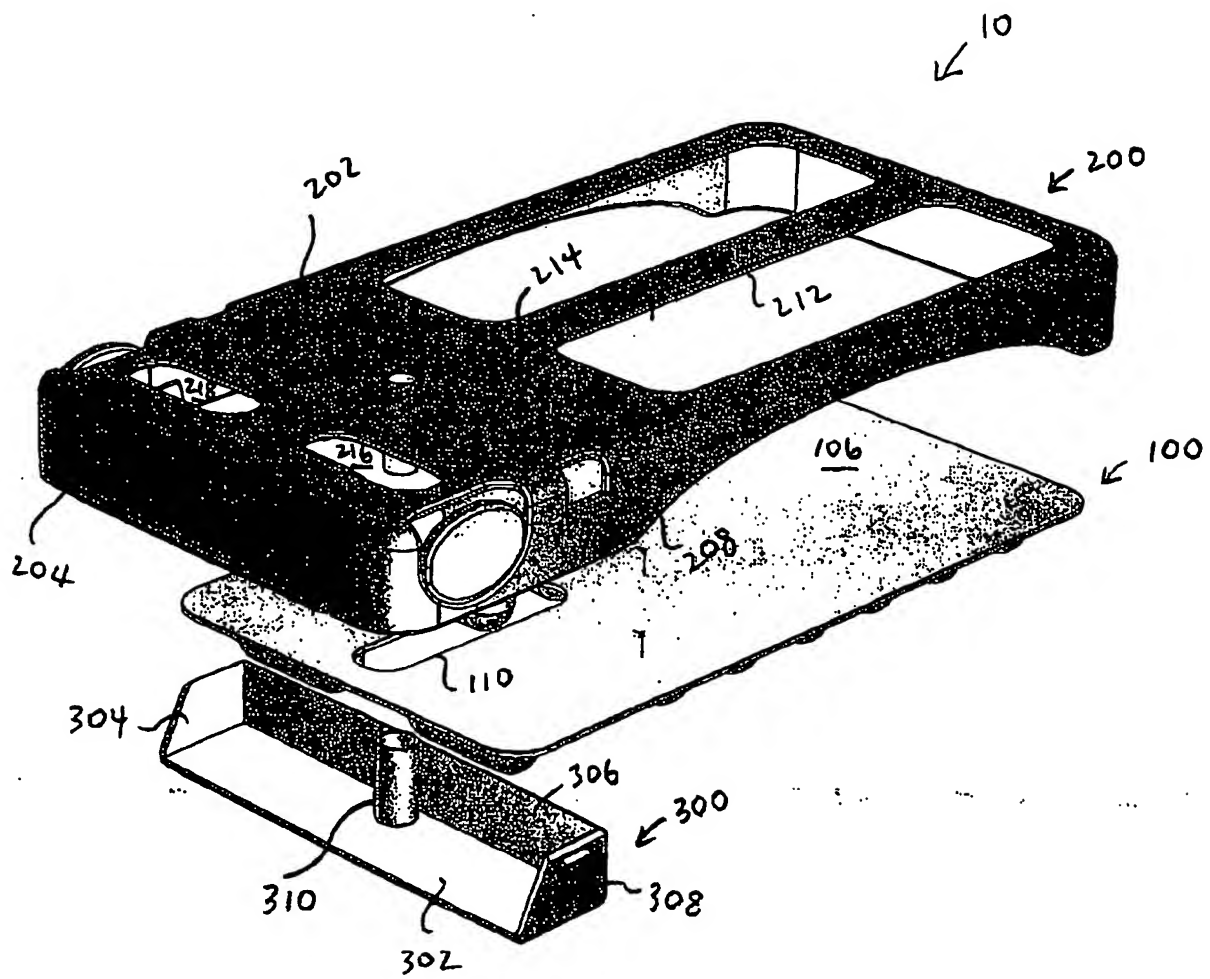


FIG. 1

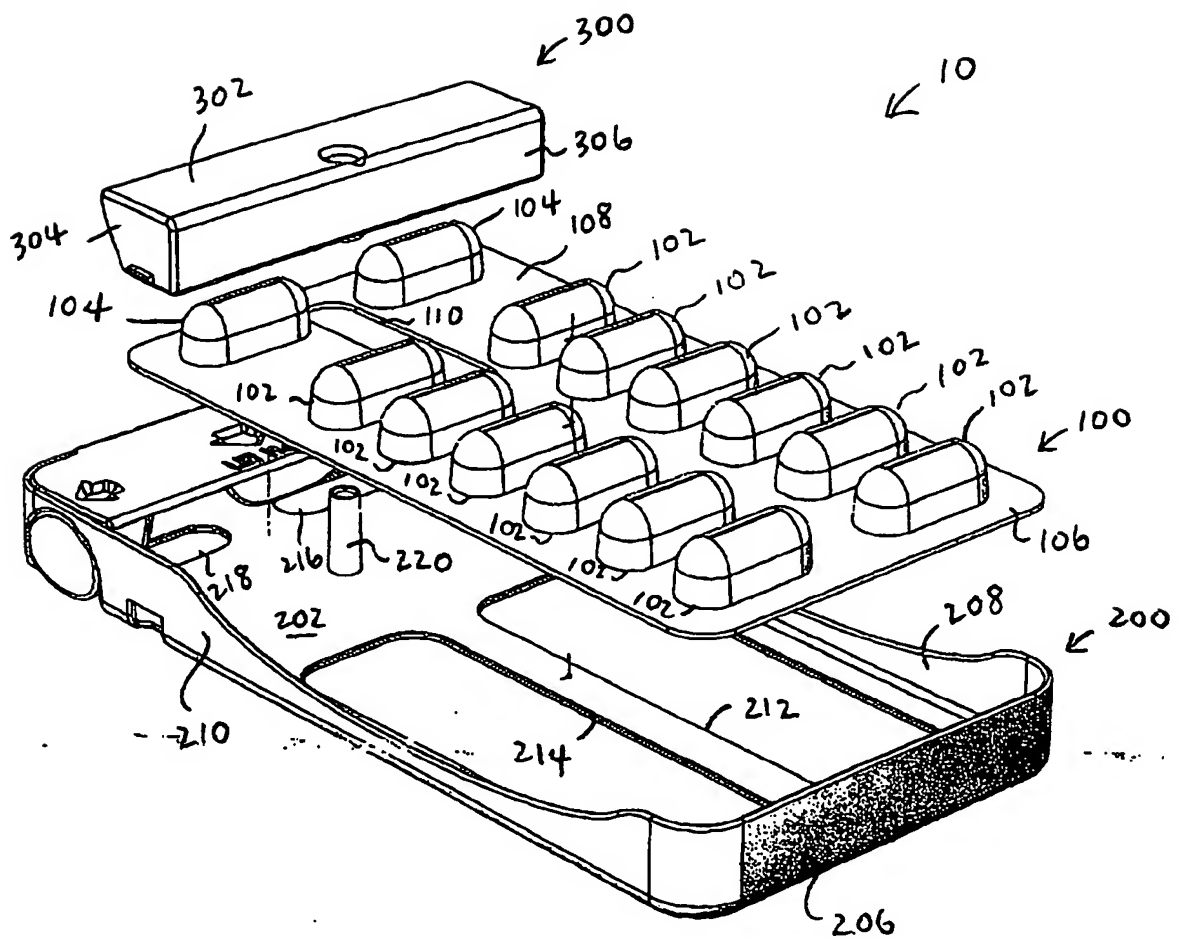


FIG. 2



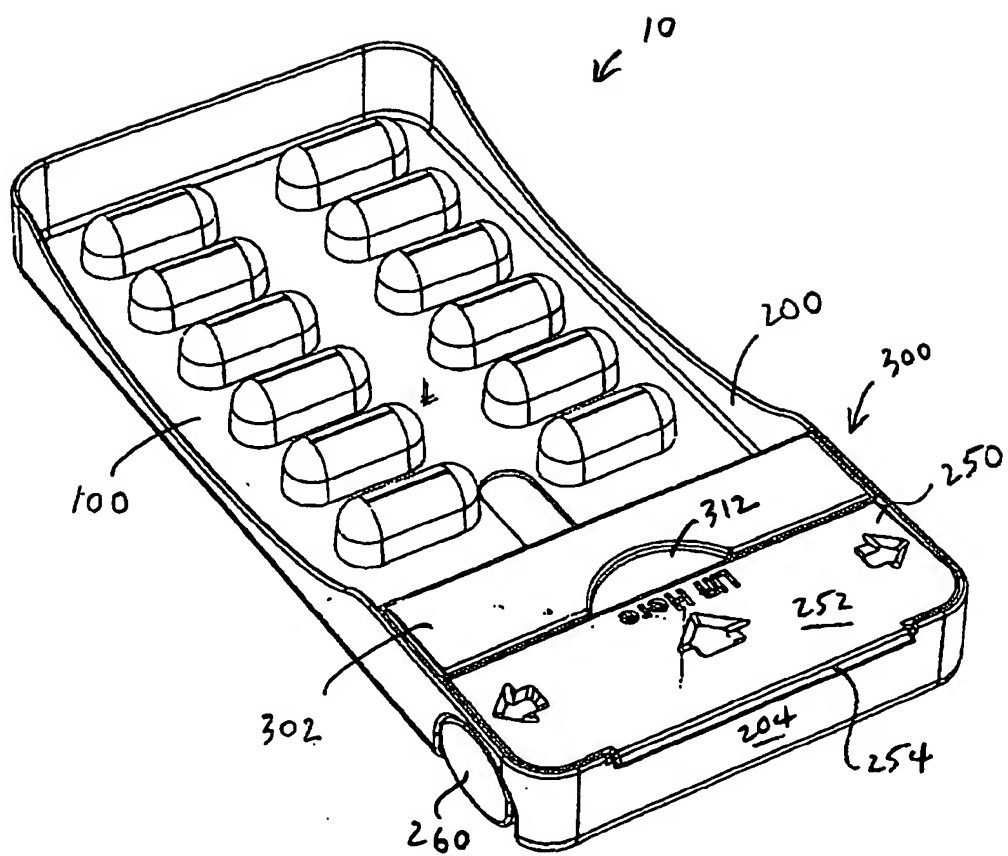


FIG. 3

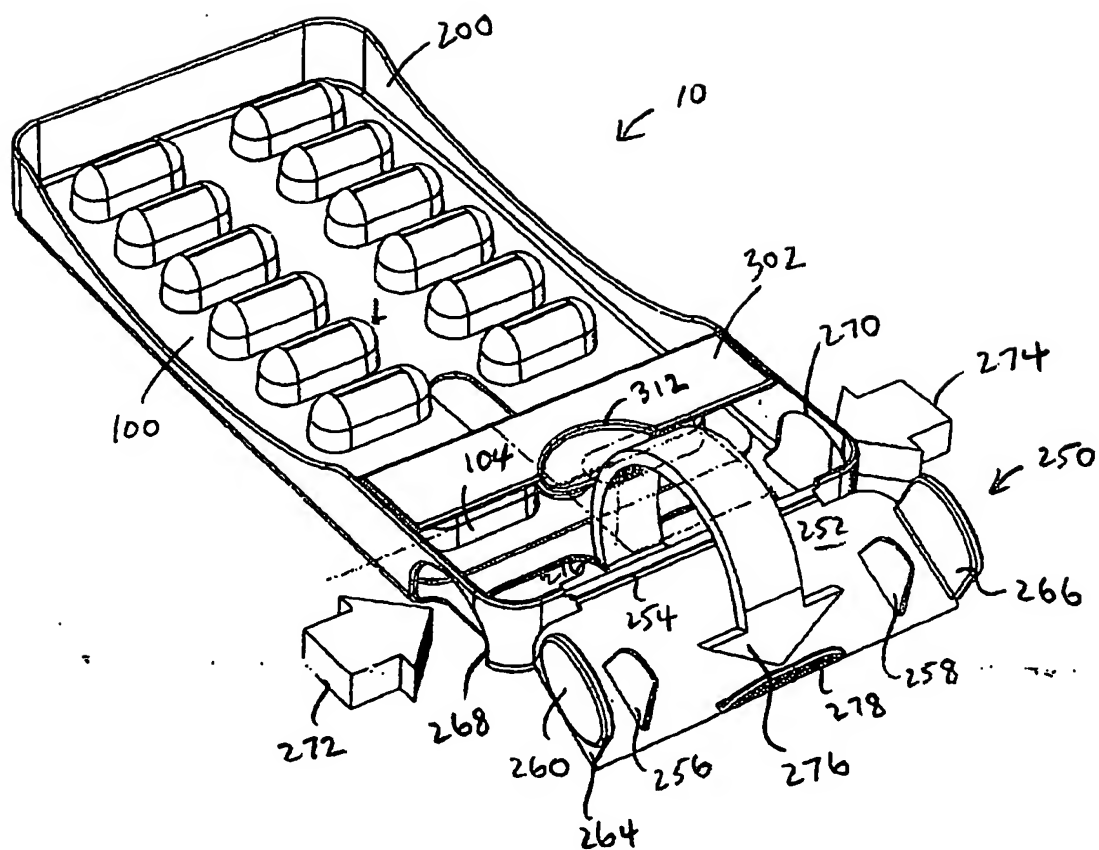


FIG. 4



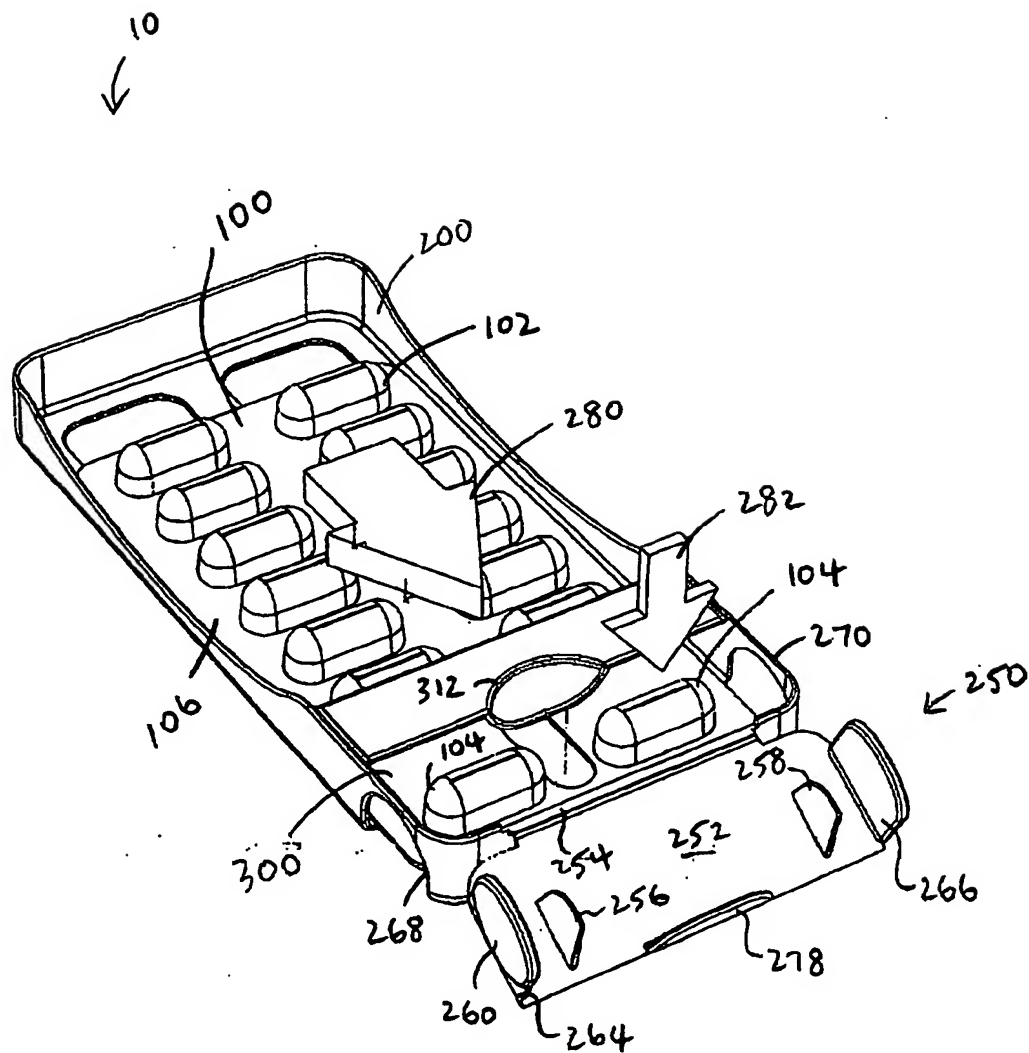


FIG. 5

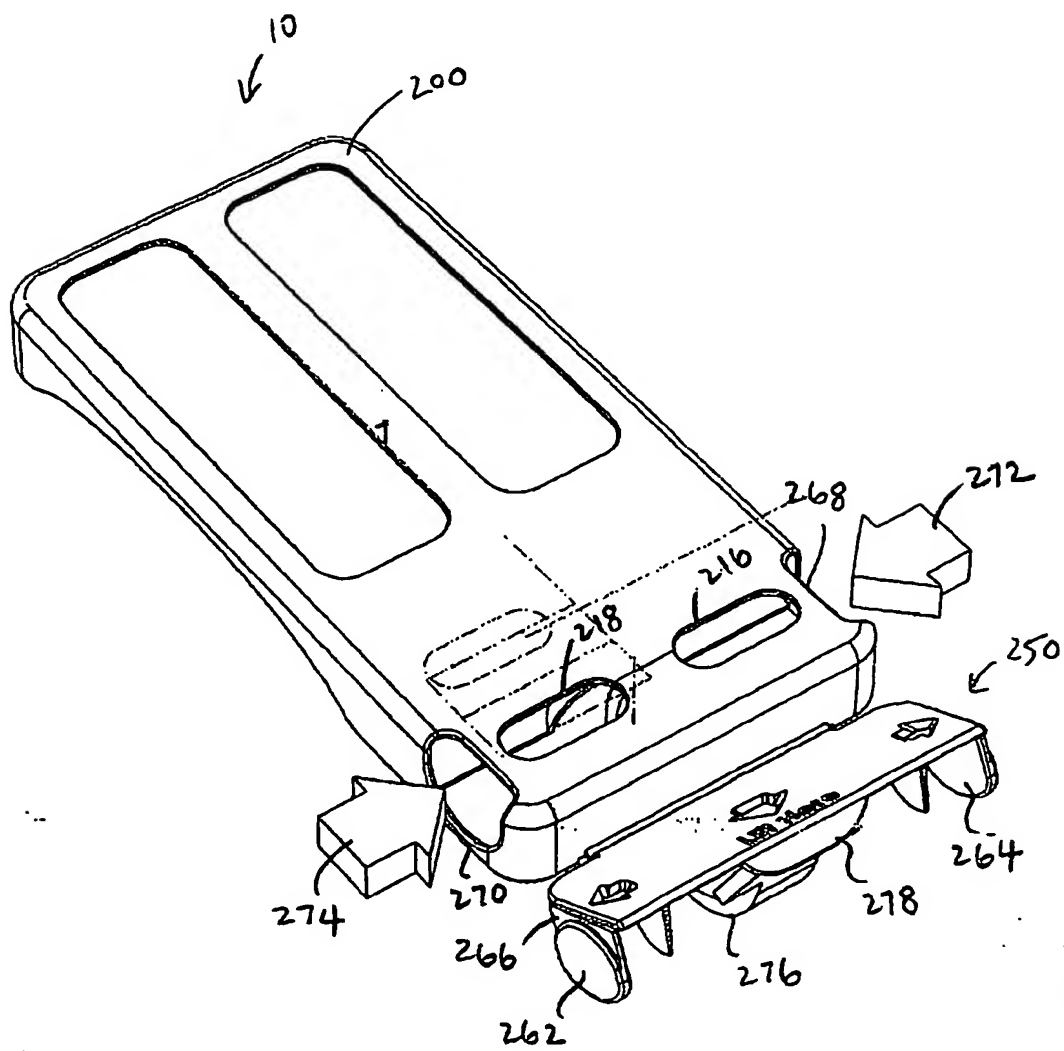


FIG. 6

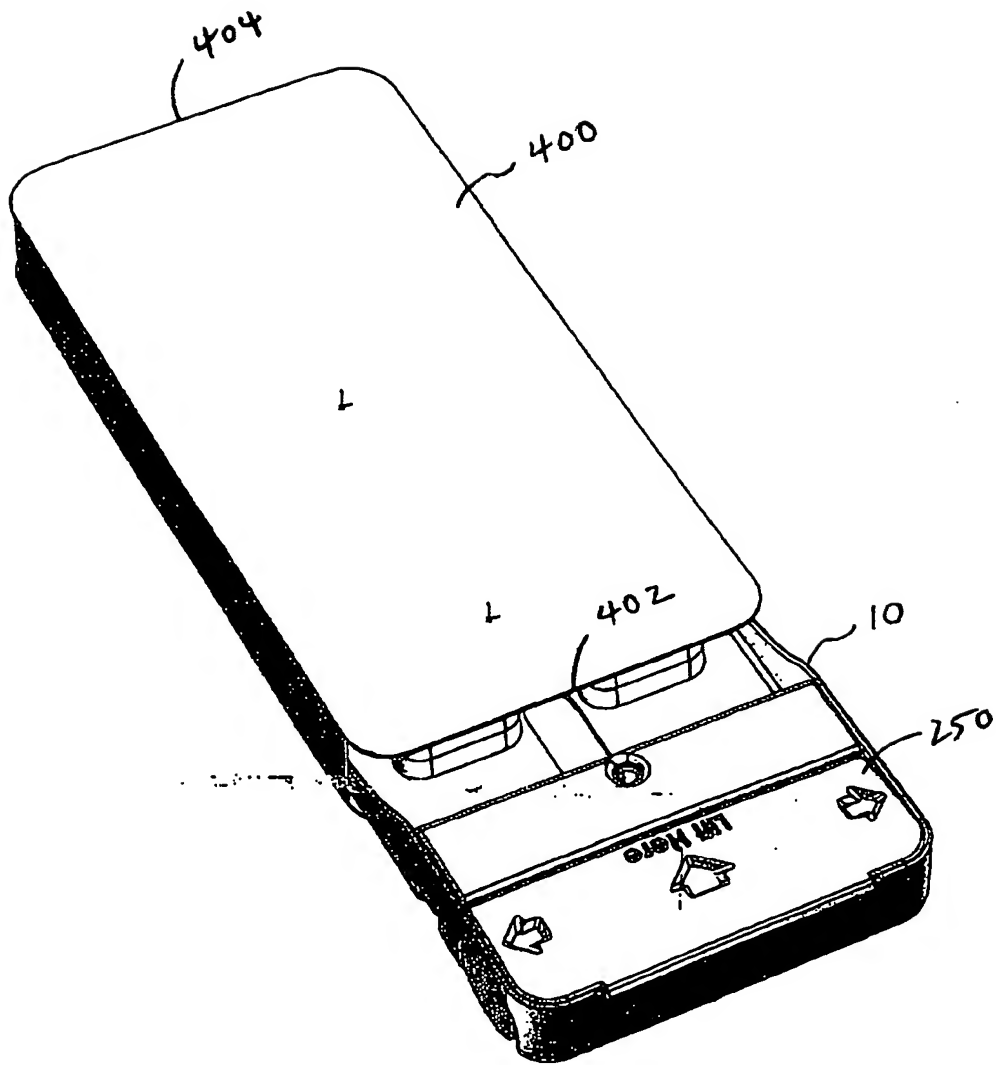


FIG. 7

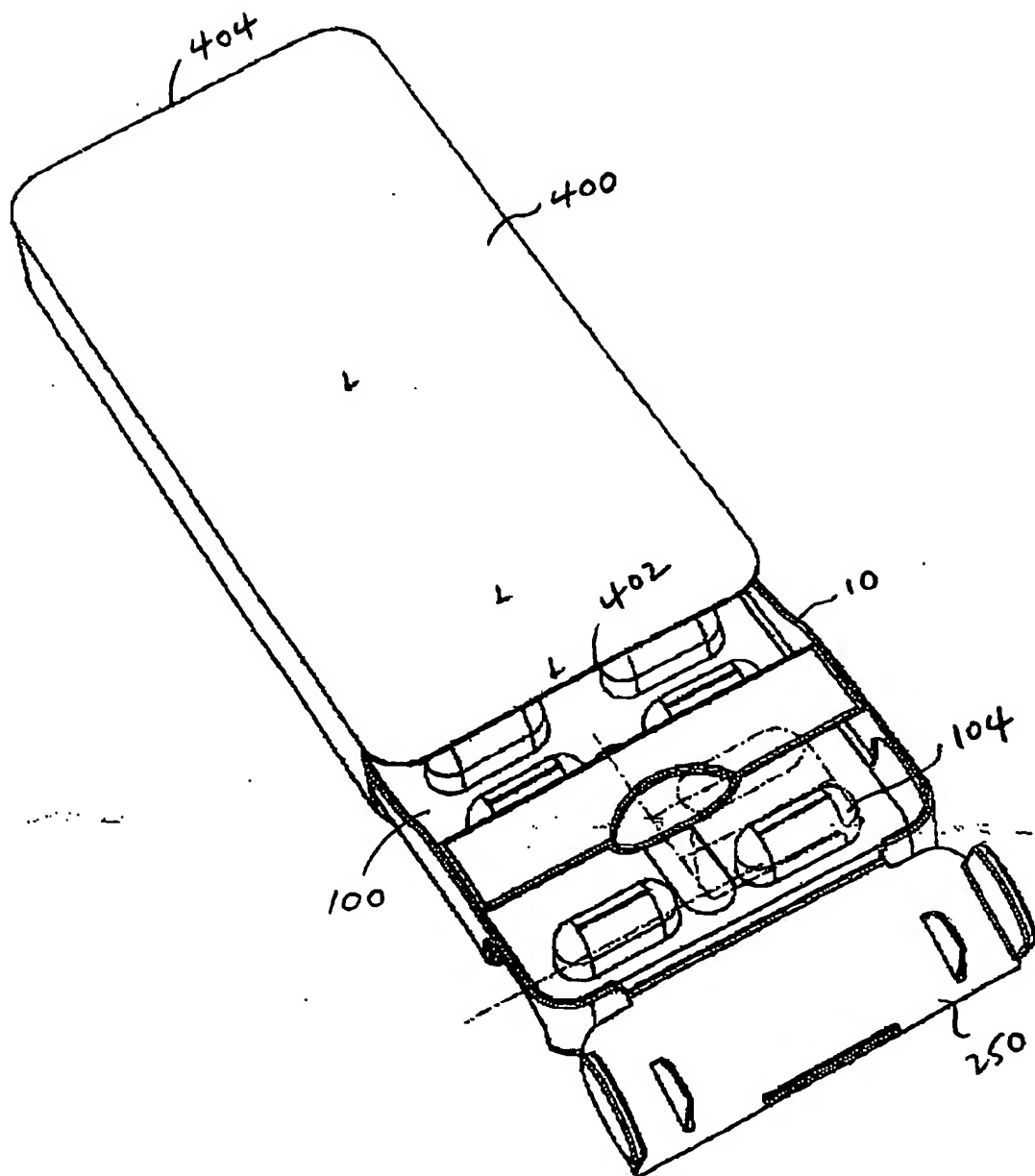


FIG. 8

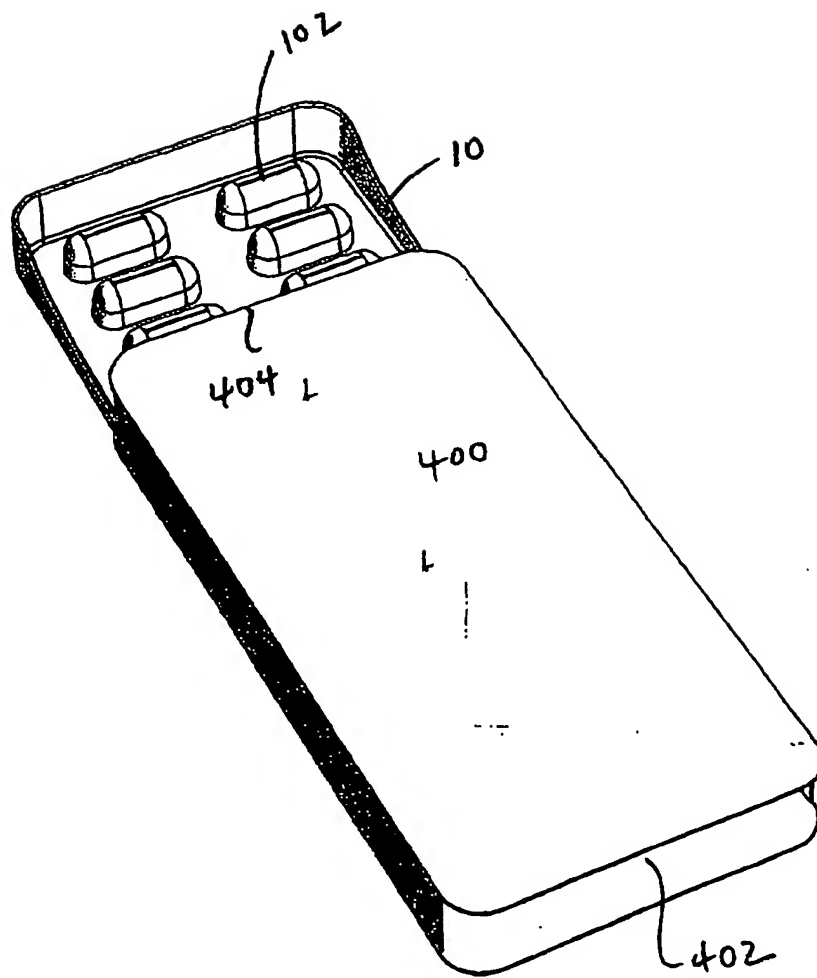


FIG. 9

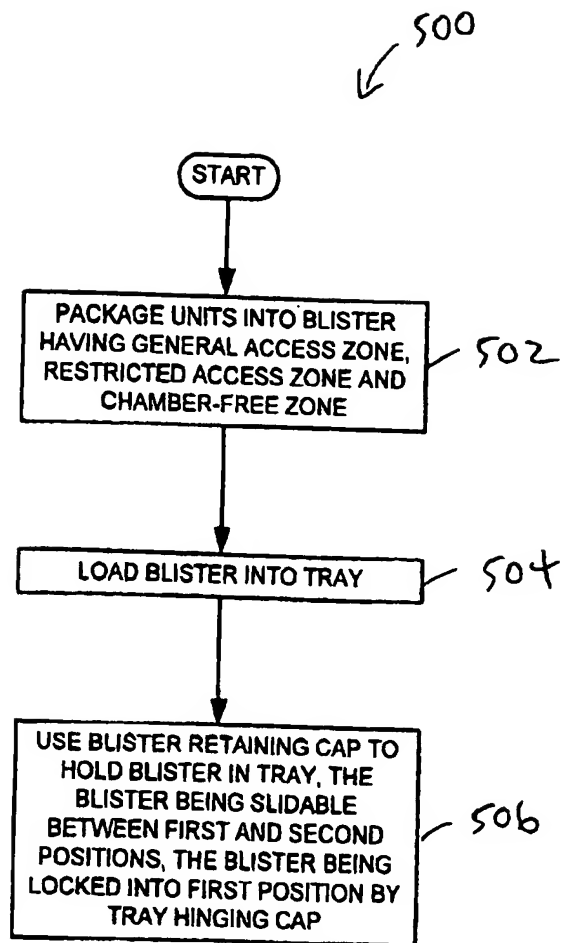


FIG. 10

Application Data Sheet

Application Information

Application number::

Filing Date::

Application Type::

Provisional

Subject Matter::

Utility

Suggested classification::

Title ::

Child-Resistant Pill Packaging System
and Method for Making Same

Attorney Docket Number::

103.0033.PROV

Suggested Drawing Figure::

Total Drawing Sheets::

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Latin name::

Variety denomination name::

Petition included?::

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Petition Type::

Licensed US Govt. Agency::

Contract or Grant Numbers::

Secrecy Order in Parent Appl.?::

No

Applicant Information

Applicant Authority Type::

Inventor

Primary Citizenship Country::

US

Status::

Full Capacity

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Postal or Zip Code of mailing address:: 10171

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- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☒ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☒ **GRAY SCALE DOCUMENTS**
- ☒ **LINES OR MARKS ON ORIGINAL DOCUMENT**
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